ORIGINAL ARTICLE

Early percutaneous transhepatic gallbladder drainage compared with endoscopic retrograde cholangiopancreatography and papillotomy treatment for severe gallstone associated acute pancreatitis

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Objective: Percutaneous transhepatic gallbladder drainage (PTGD) was compared with endoscopic treatment (within 72 hours after the onset of symptoms) in patients with severe biliary pancreatitis to evaluate the curative effect of PTGD in preventing bile track complications in these patients.

Methods: Eligible patients were randomised to receive early treatment with PTGD or endoscopic treatment. If the initial emergency endoscopic or PTGD treatment failed, patients received another drainage treatment within 24 hours. From November 2001 to August 2005, 101 patients were randomly assigned to early PTGD (n = 51) or endoscopic retrograde cholangiopancreatography (ERCP) (n = 50). Overall mortality, mortality due to pancreatitis and complications were compared in these two groups.

Results: 48 of 52 patients were successfully treated with ERCP and 53 of 55 with PTGD. Seven patients (6.9%; three in the endoscopic treatment group and four in the PTGD group) died within four months after the onset of pancreatitis (p = 0.798); three patients in the endoscopic group and three in the PTGD group died from acute biliary pancreatitis. The overall rate of complications was similar in the two groups and there were no major differences in the incidence of local or systemic complications.

Conclusions: PTGD treatment is a simple, convenient and effective treatment of severe gallstone associated acute pancreatitis when endoscopic treatment fails.

In China, gallstones account for approximately 50–70% of cases of acute pancreatitis.^{1–2} The pathogenesis of acute biliary pancreatitis is not fully understood and may be multifactorial.^{3–8} Most gallstones that initiate an episode of acute pancreatitis pass spontaneously through the ampulla of Vater into the duodenum and can subsequently be recovered in the faeces within a few days. It is uncertain whether or not early surgical or endoscopic removal of gallstones is beneficial in mild gallstone associated acute pancreatitis (GAP).^{9–10} However, early endoscopic retrograde cholangiopancreatography (ERCP) with or without endoscopic sphincterotomy has been advocated to reduce complications in patients with a severe attack of GAP.^{9–12}

Although early endoscopic intervention is the procedure of choice in patients with stone impaction and cholangitis, some patients are unable to tolerate endoscopic intervention, especially those with early severe pancreatitis who have developed organ failure within 72 hours after the onset of pain.¹³ Therefore, it is not sufficient to rely solely on endoscopic treatment to release bile matter in severe GAP. We need to find alternatives for those patients who fail to be cured by endoscopic treatment.

Percutaneous transhepatic gallbladder drainage (PTGD) has been widely accepted as an alternative to operative decompression in critically ill patients with cholecystitis or cholangitis, especially in the elderly.^{14–16} However, little is known about the factors affecting the outcome of PTGD in severe GAP. In clinical practice, we have been successful in using PTGD in some patients who were unable to receive endoscopic intervention and had complicating obstructive jaundice. In this study, we have performed a prospective, randomised trial to compare early PTGD (within 72 hours after the onset of symptoms) with endoscopic treatment in patients with severe GAP.

METHODS

Study design

We have presumed that ERCP and PTGD results in similar clinical outcomes in patients with severe GAP. Patients who satisfied the inclusion and exclusion criteria listed in boxes 1 and 2 were studied. Patients were randomly assigned in a single blind manner to receive early PTGD or endoscopic treatment (fig 1). Assignment to a treatment group was made using sealed envelopes. If the initial emergency endoscopic or PTGD treatment failed, patients received other drainage treatment within 24 h. If the subsequent treatment was successful, patients were assigned to that treatment group; if not, patients were excluded from the study.

Research and observation were chiefly aimed at assessing the rate of mortality resulting from this disease 4 months after the patient had been hospitalised for observation. (Those who recovered and were discharged from hospital within 4 months of treatment were defined as survivors). The second aim was the success rate of effectively preventing biliary duct problems. Systemic complications included renal failure, respiratory failure, cardiogenic shock, bleeding gastric erosions and disseminated intravascular coagulopathy. Assessment of outcome was based on the development of local complications (pancreatic abscess, pseudocyst, phlegmon and bleeding pseudoaneurysm) as well as the success rate of the two forms of treatment and the complications resulting from the operation itself.

Haemodynamic, pulmonary, renal, haematological, serum bilirubin levels and coagulation variables, including

Abbreviations: ERCP, endoscopic retrograde cholangiopancreatography; GAP, gallstone associated acute pancreatitis; PTGD, percutaneous transhepatic gallbladder drainage

Box 1: Criteria for inclusion of patients in the trial of percutaneous transhepatic biliary drainage compared with endoscopic treatment

- Pain in the upper abdomen
- Serum amylase or lipase levels higher than three times the upper limit of normal
- Signs of acute pancreatitis on ultrasonographic or computed tomographic scans
- Diagnosis of severe acute pancreatitis, as defined by the clinical criteria of the Atlanta Symposium
- Biliary cause of pancreatitis^{19 20}
- Ability to perform PTGD or endoscopic treatment within 72 h after the onset of pain
- Age >18 years
- Provision of written informed consent

PTGD, percutaneous transhepatic gallbladder drainage

APACHE and MODS scores, were monitored at admission, on days 2, 3, 5, 7, 14 and 21 days, and at discharged from hospital. Pancreatitis was assumed to have a biliary origin if gallstones were seen on ultrasonographic or computed tomographic scans or if two of the following three laboratory abnormalities were present: elevated alkaline phosphatase level (>125 U/l), elevated alanine aminotransferase level (>75 U/l) or an elevated bilirubin level (>2.3 mg/dl (39 µmol/l)).^{17 18}

In those patients assigned to receive emergency PTGD, the procedure was performed under local anaesthesia using ultrasonographic guidance. Ultrasonographic guided transhepatic gallbladder drainage was performed at the bedside in the intensive care unit. An 18 F spinal needle was positioned transhepatically in the gallbladder and bile was aspirated and cultured. The Seldinger technique was used to place an 8.3 F pigtail catheter. When available, the location of the gallbladder drainage catheter was verified by fluoroscopy following injection of a water soluble contrast material. For those patients assigned to receive emergency ERCP, the procedure was performed in a standard manner with the goal of selective cannulation of the common bile duct and avoidance of the pancreatic duct. If one or more stones were identified, endoscopic papillotomy was performed with a cutting needle for ampullary stones or a papillotome for common bile duct stones. If stone removal was incomplete, a nasobiliary drainage catheter was inserted.

Statistical analysis

Continuous variables are expressed as mean (SEM) and clinical findings as percentages, unless otherwise stated. To compare group mean values, the Mann–Whitney U test was used to compare continuous variables while the χ^2 test (with Yates' correction if there were less than 10 cells) and Fisher's exact test were used to compare discrete variables. Differences in complication rates between the two groups were compared by one way ANOVA. All p values <0.05 were considered significant (by the two tailed test). Statistical calculations were performed using SPSS and Nanostat computer software.

RESULTS

From November 2001 to August 2005, 219 consecutive patients in the SICU of Jinling Hospital, Nanjing, a 17 bed unit, were suspected of having severe GAP. A total of 115 patients could not be randomly assigned to a treatment group because of

Box 2: Criteria for exclusion of patients in the trial of percutaneous transhepatic biliary drainage compared with endoscopic treatment

- Pregnancy
- Coagulation abnormalities
- Alcoholism or metabolic cause of pancreatitis
- Need for urgent operation and necrosectomy, had simultaneous cholecystectomy
- Patients simultaneously included in any other study

symptoms requiring early endoscopic or PTGD treatment (103 patients had an onset of symptoms more than 72 hours before endoscopic or PTGD treatment could be performed, eight refused to participate and four were <18 years of age). The remaining 104 patients were randomly assigned to early PTGD (n = 52) or ERCP management (n = 52). Three patients (two in the ERCP group and one in the PTGD group) did not meet all of the inclusion criteria after randomisation, leading to failure of screening. In two patients, ERCP could not be performed within 72 hours after commencement of symptoms, and one patient in the PTGD group had coagulation abnormalities. These three patients were excluded from the study. Hence 101 patients were included in the final analysis, 50 in the ERCP group and 51 in the PTGD group. There were 56 males and 45 females, and median age was 52.8 years (range 21–91). There were no significant differences in age or sex distribution between the two groups (p<0.05). Median Ranson score was 4 (range 0–9), median APACHE-II score at admission was 13 (range 8–29) and median MODS score at admission was 5 (range 0–14). Sixty nine patients were admitted to our hospital and 32 were referrals from other hospitals.

Results of PTGD and ERCP

In the first treatment step, 50 patients received early ERCP and in four (8%) the treatment failed (two patients were unable to receive endoscopic intervention because of complicating acute respiratory distress syndrome and the need for tracheal intubation). All four patients were successfully treated with PTGD. Fifty one patients received PTGD initially and in two (3.9%) the treatment failed. These two patients were successful treated with ERCP. In total, 48 of 52 patients were successfully treated with ERCP (92.3%) and 53 of 55 with PTGD (96.3%). There were no significant differences in the success rate between the two groups (p = 0.362). With regard to comparison of the curative effect, 53 (PTGD) of 101 patients who received endoscopic treatment were successful compared with 48 patients who were treated with ERCP. There were no significant differences in age, sex distribution, Ranson score, APACHE-II score or MODS score between the two groups (table 1).

In the PTGD group, all 53 patients were able to receive treatment. The only major complication (1.9%) was related to a bleeding liver laceration that was successfully managed by haemostatic therapy and two units of blood (table 4). One patient had minor peritonitis for bile leakage which was controlled by non-operative treatment. In the endoscopic intervention group, one patient (2.1%) had bleeding after the papillotomy and needed three units of blood. The bleeding was controlled by local injection of epinephrine (at a dilution of 1:10 000) during a second endoscopy. There were no other immediate complications, such as perforation of the duodenal wall, in the ERCP group. There were no significant differences in complications rates following invasive treatment in the two groups (table 2).

Figure 1 Emergency drainage steps in patients who met the study criteria.

Mortality and complications

Seven patients (6.9%), three in the endoscopic treatment group and four in the PTGD group, died within 4 months after the onset of pancreatitis ($p = 0.798$) (table 3). Three patients in the endoscopic group and three in the PTGD group died as a direct result of GAP ($p = 0.900$) (table 3). One patient in the PTGD group died of causes unrelated to pancreatitis. Death was caused by cerebral infarction during the restoration period of pancreatitis. All patients who died were older than 50 years (52–81 years in the endoscopic group and 62–90 years in the PTGD group).

No patient required emergency surgical intervention because of biliary sepsis in either group. In the PTGD group, one patient had acute cholecystitis, and ERCP was performed 16 days after PTGD because of increasing jaundice. The success rate of effectively preventing problems with the biliary duct was 100% in the ERCP group and 98.1% in the PTGD group, with no significant difference between the two groups ($p = 1.00$). The overall rate of complications was similar in the two groups but patients in the PTGD group had more severe complications (table 3). Complications occurred in 31 (64.6%) patients in the ERCP group and in 39 (73.6%) in the PTGD group (table 3). There were no major differences in the incidence of local complications (28 of 53 patients who underwent emergency PTGD compared with 27 of 48 patients who received ERCP treatment; $p = 0.588$) or systemic complications (23 of 53

patients compared with 24 of 48 patients, respectively; $p = 0.506$) (table 3).

DISCUSSION

Acute biliary pancreatitis is initiated by obstruction of the ampulla of Vater by migratory gallstones or by a spastic sphincter of Oddi.^{3–8 19 20} Persistent ampullary obstruction may be responsible for the progression from pancreatic oedema to haemorrhage and necrosis.⁶ Biliary sepsis or other complications develop in some patients. Among such patients, mortality has been found to be 13–50%.^{21–23} Early surgical removal of biliary stones has been advocated to prevent these complications. However, early in the course of severe GAP, patients are at high risk of death from cardiovascular or pulmonary failure and early surgical intervention is favoured, especially in the presence of deteriorating systemic organ function, but is associated with a much higher morbidity and mortality rate.^{24–27} Hence there is general agreement that abdominal surgery is not advocated for acute pancreatitis in the early stages unless the patient is suffering from severe abdominal compartment syndrome with complications, cholangitis or progressive decline of function of several organs, and active medical care and treatment or minimally invasive surgery have failed.

At present, it is well known that that early ERCP with or without endoscopic sphincterotomy can reduce complications

Table 1 Characteristics of the 101 patients who received PTGD or endoscopic treatment on admission

Characteristic	PTGD treatment (n = 53)	Endoscopic treatment (n = 48)
Sex (M/F)	29/24	27/21
Age (y)	54 (24–91)	51 (21–85)
Body temperature (°C)	38.1 (35.5–39.8)	38.1 (35.7–39.4)
Serum amylase (IU/l)	2520 (1020–14 540)	2480 (1010–12 480)
Serum bilirubin (mg/dl)	2.2 (0.3–30.7)	2.3 (0.3–32.7)
Serum urea nitrogen (mg/dl)	25 (9–139)	23 (8–54)
Plasma glucose (mg/dl)	189 (78–512)	181 (81–432)
Ranson's score	4 (0–9)	4 (0–8)
APACHE II score	14 (8–29)	12 (8–27)
MODS score	5 (0–14)	4 (0–13)

PTGD, percutaneous transhepatic gallbladder drainage.

Values are median (range).

To convert values for bilirubin to $\mu\text{mol/l}$, multiply by 17.1; to convert values for urea to mmol/l , multiply by 0.357; and to convert values for glucose to $\mu\text{mol/l}$, multiply by 0.0556.

Table 2 Success rate and complications of invasive treatment in the two groups

Variable	PTGD treatment (n = 53)	Endoscopic treatment (n = 48)
Time from admission to invasive treatment (median (range))	24 (2–40)	24 (2–54)
Success rate (%)	53/56 (96.3)*	48/52 (92.3)†
Major complications		
Bleeding	1	1
Bile leak	1	0
Perforation of the intestinal wall	0	0
Abdominal pain	3	2

*51 patients received early PTGD treatment initially, and 49 were treated successfully. In four patients ERCP treatment failed but all successfully received PTGD.

†In the first treatment step, early ERCP failed in four of 50 patients. Two patients who initially failed PTGD treatment were successfully treated with ERCP.

in patients with a severe attack of GAP.^{11 12 28 29} Such treatment causes only minor trauma and can effectively prevent deterioration of organ function which can be caused by early operation. In clinical practice, however, some patients develop organ failure at an early stage after the onset of pain and cannot receive endoscopic treatment. Therefore, it is necessary to find alternative treatments for severe GAP, rather than resorting to endoscopic treatment and major abdominal surgery. In recent years ultrasound or computed tomography guided PTGD treatment has replaced open cholecystostomy for the treatment of acute cholecystitis in critically ill patients. In this study, we performed a prospective, randomised, single centre trial to compare early PTGD (within 72 hours after the onset of symptoms) with endoscopic treatment in patients with severe GAP in terms of their prognosis, ability to eliminate problems with the biliary duct as well as overall and local complications resulting from pancreatitis.

In our study, there were no significant differences in the rate of complications of the two invasive treatment groups, despite one case of bleeding in each group, and there were no other serious complications. The success rate in two groups was similar. However, two patients could not tolerate endoscopic intervention because of complicating acute respiratory distress

syndrome and the need for tracheal intubation. Comparatively speaking, PTGD treatment can be performed at the bedside in the ICU and can be endured by even the most severe cases.

We found no marked difference in prognosis between PTGD and endoscopic treatment in patients with severe GAP. The incidence of local and systemic complications was similar in the two groups. Biliary sepsis was effectively avoided in the two groups, and no patient required emergency surgical intervention for biliary sepsis.

Compared with PTGD, endoscopic treatment can clear out the biliary tract directly by ERCP with or without endoscopic sphincterotomy. The reduction in pressure of the bile duct after PTGD depends on the smoothness of the duct of the gallbladder. In some patients with GAP, no stones can be found in the bile duct. The reason for the obstruction of the ampulla is spasm of the sphincter of Oddi caused by inflammation of the gallbladder.^{3–8} Even if the obstruction of the ampulla results in migratory gallstones, most gallstones that initiate an episode of acute pancreatitis pass spontaneously through the ampulla of Vater into the duodenum and can subsequently be recovered in the faeces within a few days. PTGD can effectively avoid the progression of gallbladder inflammation with ensuing gangrene or perforation and so

Table 3 Complications and in-hospital mortality among patients with acute pancreatitis, according to treatment group and predicted severity of disease

Variable	No of patients (%)		p Value
	PTGD treatment (n = 53)	Endoscopic treatment (n = 48)	
Total	39 (73.6)	31 (64.6)	0.327
Death	4 (7.5)	3 (6.3)	0.798
From acute pancreatitis	3 (5.7)	3 (6.3)	0.900
From other causes	1 (1.9)	0	1.000
Local complications			
Pancreatic abscess	6 (11.3)	5 (10.4)	0.884
Pancreatic necrosis	28 (52.8)	27 (56.3)	0.730
Pancreatic pseudocyst	12 (22.6)	10 (20.8)	0.826
Systemic complications			
Respiratory failure	19 (35.8)	21 (43.8)	0.417
Cardiovascular shock	11 (20.8)	9 (18.8)	0.801
Bleeding gastric erosions	3 (5.7)	4 (8.3)	0.597
Disseminated intravascular coagulopathy	3 (5.7)	2 (4.1)	0.730
Jaundice	3 (5.7)	1 (2.1)	0.357
Biliary sepsis			
Acute cholangitis	0	0	1.00
Acute cholecystitis	1 (1.9)	0	1.00

*Some patients had more than one complication. Respiratory failure was considered to be present the partial pressure of oxygen could not be maintained above 60 mm Hg with an oxygen mask. Renal failure was defined as oliguria lasting more than 24 hours. Cardiovascular shock was considered to present if an inotropic agent was required for more than 24 hours to maintain the systolic blood pressure at a level higher than 100 mm Hg. Jaundice was defined as a bilirubin levels exceeding 5 mg/dl.

release the obstruction of the ampulla of Vater caused by the spasticity of the sphincter of Oddi allowing most gallstones to pass through the ampulla of Vater into the duodenum. Although we did not compare PTGD treatment with conventional treatment in this study, only one patient (1.9%) developed complications of biliary sepsis in the PTGD treatment group which is lower than that of conventional treatment reported previously.^{9 10}

This study was a single centre trial with a small sample size and hence definitive conclusions cannot be drawn with regard to PTGD treatment and endoscopic treatment. Furthermore, in view of the ethic factors, we did not compare PTGD treatment with conventional treatment. Hence we cannot make assumptions about PTGD treatment compared with conventional treatment. However, the curative effect of PTGD and endoscopic treatment was similar in our study. In treating critically ill patients, PTGD may be an alternative therapy in severe GAP to prevent bile track complications.

In conclusion, the safety and effectiveness of PTGD and its minimal invasiveness^{14 15 18 30 31} have made it an effective option for treating patients who cannot tolerate endoscopic treatment. Moreover, many patients in developing countries have no medical access to endoscopic treatment at the early stages of severe GAP. Therefore, PTGD may be a simple, convenient and effective treatment for severe GAP.

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